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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,375	03/05/2002	Lawrence C. Smith	1051-1-020	6403

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EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,375

Applicant(s)

SMITH ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 15, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed June 15, 2005 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-18 and 20-38 are pending and subject to the examination below.

Applicant's amendment has overcome the rejection made in the office action mailed February 12, 2005 under 35 U.S.C. § 112, second paragraph.

Applicant's arguments have overcome the rejection made in the office action mailed February 12, 2005 under 35 U.S.C. § 103 over Schnieke et al in view of Bordignon.

Applicant's amendment has overcome the rejection made in the office action mailed February 12, 2005 under 35 U.S.C. 112, first paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-27 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by from the sheep embryos, sheep fetuses and live-born sheep of Schnieke. Schnieke et al. Science, 1997, Vol. 278, pp. 2130-2133 for reasons presented in the office action mailed February 12, 2005.

Schnieke teaches the production of transgenic sheep comprising a DNA sequence encoding factor IX by nuclear transfer where the donor cell was a fibroblast transfected with the DNA sequence (page 2130, col. 3, parag. 3 to page 2131, col. 2, lines 6 and page 2131, col. 3, parag. 1 and 2). Schnieke teaches that transgenic embryos and fetuses were produced by the method (page 2131, Table 1). There is no evidence that the method of making the claimed products alters them such that they can be distinguished.

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Applicant argues unexpected results in the number of embryos that developed to term offspring. Applicant argues declarant Lawrence Smith states 40% of nuclear transfer embryos develop into offspring when a nucleus is transferred into a telophase II oocyte. These arguments are not persuasive.

Applicant has not indicated where in the Smith declaration this can be found. The only place where "40%" can be found is in Table 1, page 8. Here, 40% of embryos produced by method 2 developed into calves. However, the oocytes used are described as being MII enucleated oocytes. Note that step "c" refers back to Method I, which states MII. There is no disclosure that telophase oocytes were used. However, even taking into consideration that an error was made in the declaration, applicant's arguments are not persuasive. The presently claimed non-primate transgenic embryo, fetus or offspring is claimed to be produced by a method much broader than that of the declaration. In arguing unexpected results the claimed invention cannot be broader than the scope of the unexpected results (see MPEP 716.02(d)). In addition, there is no disclosure in the specification of using roscovitine arrested donor cells. A declaration can only support that which is disclosed and not provide new elements of the invention. Also use of confluent arrested fibroblasts as donors is not disclosed in the specification. There must be a nexus between that taught in the specification and the declaratory evidence (see MPEP 716.01(b)). Further unexpected results are only persuasive for obviousness rejections, and not anticipatory rejection (see MPEP 2131.04). For these reasons the Smith Declaration is not persuasive.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29,

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2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-18 and 20-38 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent 6,580,017 B1 issued June 17, 2003 (Echelard) for reasons presented in the office action mailed February 12, 2005 and June 23, 2004.

Echelard teaches methods for the production of reconstructed goat oocytes, reconstituted goat embryos, methods for the production of transgenic goat embryos, a method of cloning a goat, methods for producing transgenic goat embryos, and methods of cloning a goat comprising incubating goat oocytes to telophase II, and then further incubating the oocyte in the presence of cytochalasin B, enucleating the activated, telophase II oocyte by aspiration or microsurgery removing second polar body and surrounding cytoplasm (col. 19, lines 6-14, and 18-26), transferring a cultured goat fetal fibroblast which contains a DNA sequence encoding antithrombin III (col. 16, lines 19-25 and lines 42-44) into the perivitelline space of the enucleated oocyte (col. 19, lines 35-40), fusing the reconstructed oocyte by electrofusion (col. 19, lines 48-52), culturing the reconstituted oocyte to produce a transgenic embryo (col. 21, lines 22-24), which is then transferred to a surrogate mother goat to produce a transgenic goat offspring (col. 21, lines 25-27 and col. 22, line 52). Echelard teaches activation by electrofusion, ethanol, ionophore or serum (col. 13, lines 40-43 and col. 15, 15-20). Echelard also teaches the fibroblast donor cells were inherently in one of G0, G1, S, G2 or M as these are all the stages of the cell cycle. Further, Echelard teaches transgenic goat embryos, fetuses and offspring. Thus, Echelard clearly anticipates the claimed invention.

Applicant argues that Echelard teaches using ethanol for treating oocytes and that this provides negative results. Applicant argues that Table 2 of Echelard demonstrates of ethanol treated telophase oocytes failed to give viable embryos and fetuses, with no development to term of transferred embryos. Applicant argues that Echelard is not

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operable. Applicant argues that Echelard does not teach or suggest enucleation of activated oocytes precisely when undergoing expulsion of a second polar body or after expelling the second polar body. These arguments are not persuasive.

As stated in the previous office action, mailed February 16, 2005, in the specific example, ethanol treated oocytes did not yield live born goats. However, ethanol was used to activate in vivo matured oocytes that arrested prior to second polar body formation/extrusion. There is no evidence in Echelard that if immature oocytes were activated at MII with ethanol that live births would not have occurred. The present specification supports this later theory. The present specification activates MII oocytes, first polar body containing, with ethanol and permits them to continue to telophase II (page 9, step 1). Thus, Echelard's disclosure of ethanol treatment as an activating agent is enabled. Table 2 clearly shows that telophase enucleated oocytes yield a twin pregnancy and the birth of 2 live-born kids. An oocyte in telophase is inherently activated, that is the telophase oocyte is in the process of extruding its second polar body. Thus the oocytes of Echelard are activated. Further, Echelard teaches "... oocytes which demonstrate a protrusion in the plasma membrane, usually with a spindle abutted to it, up to extrusion of the second polar body are considered to be oocytes in telophase" (col. 14, lines 32-35). In support applicant is referred to col. 19, lines 5-11, which states enucleation took place after extrusion of a second polar body. Thus, Echelard teaches a range of times for enucleation which encompass the precisely when the oocyte is undergoing expulsion of the second polar body. Thus Echelard teaches enucleation precisely when the oocyte is undergoing expulsion of the second polar body. In addition, Echelard specifically teaches enucleation of telophase II oocytes by aspirating the extruded second polar body (telophase spindle) (col. 19, lines 21-25). Thus, Echelard does teach both enucleation of activated oocytes precisely when

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undergoing expulsion of the second polar body or after the second polar body had been expelled.

Applicant argues that conceived their invention prior to November 1998, the priority of US Patent 6,580,017 (Echelhard). Declarant Smith provides a copy of a research grant proposal as evidence of earlier conception. These arguments are not persuasive.

A declaration under 37 CFR 1.131 does not overcome a rejection under 35 U.S.C. § 102(e) as applicant's claims and Echelhard's claims are to the same invention (see MPEP 706.02(b), "D" under 102(e)). Applicant is advised to review MPEP 2306 and determine if an interference proceeding would be proper and file the appropriate request.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

July 27, 2005